Standards for therapeutic vaping devices

If you are a sponsor intending to supply a therapeutic vaping device, you can seek TGA approval by including your device in the Australian Register of Therapeutic Goods (ARTG), or you can use the unapproved goods pathway, by submitting a notification to import and supply your device.

To submit a notification, you must either notify compliance with the Essential Principles (EPs) for medical devices, or, if the vaping device was previously excluded from the therapeutic goods framework because it was not intended exclusively to administer a medicine, you can notify compliance with the Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023 (the MDSO). Detailed information about the regulatory requirements and pathways for different therapeutic vaping devices, including about the MDSO, can be found in the guidance for therapeutic vapes.

How can this document help you?

If you intend to claim compliance with the EPs the following checklist provides a range of industry standards and guidance that can help you to ensure that your device complies with the EPs. No single standard satisfies all EP requirements. We have developed the checklist to help you determine the best way to demonstrate that your product meets the EPs. This information may also help you if you are considering including your device on the ARTG.

Vaping devices and the Essential Principles

Generally, manufacturers of medical devices must generate, collate, assess, and maintain scientific and engineering evidence that shows that their devices comply with the EPs. The evidence must relate to the device's intended purpose and must be objective and comprehensive. Compliance with industry standards is the normal way to demonstrate that a medical device meets the EPs.

Once you have established evidence that your vaping device complies with the EPs, you should complete the Essential Principles checklist before you submit your notification to the TGA. We may request this information or any evidence relating to statements in your notification, including about compliance with the EPs.

If you need expert help to ensure your device complies with the EPs, some industry organisations may be able to help you find a medical device regulatory affairs consultant.

Including a therapeutic vaping device on the ARTG

You are encouraged to seek a pre-submission meeting with TGA if you intend to seek TGA approval for your therapeutic vaping device. Please do this early in your planning to ensure you understand the regulatory requirements for including a therapeutic device in the ARTG.

Standards to help demonstrate a therapeutic vaping device complies with the Essential Principles

The following checklist is designed to help you if you intend to claim compliance with the EPs, however it is not exhaustive as there are many other standards or sources of information you could use. Compliance with one or more of the standards listed does not mean you meet all the regulatory requirements.

Notes for the checklist:

- If a standard listed in the checklist table has a tick, that standard may help you demonstrate compliance with the corresponding EP, or part of that EP.
- To ensure full compliance, the manufacturer or sponsor of the device should undertake a gap analysis to assess if EP requirements are met by the nominated standard, and to ensure all applicable EPs have been met.
- You could use industry standards for e-cigarettes to establish evidence of compliance to some of the EPs (or parts of them). However, standards such as CEN/TS 17287 - Requirements and test methods for electronic cigarette devices are not sufficient to demonstrate compliance with all the EPs. These standards alone do not support therapeutic use.
- If your device contains button or coin batteries, the *Consumer Goods (Products Containing Button/Coin Batteries) Safety Standard 2020* is mandatory in Australia.

Standards checklist for therapeutic vaping devices

Tick here when you have evidence for this EP	EP No	EP Description	ISO 14971	ISO 20072	CEN/TS 17287	Other relevant standards and guidance documents
☐	EP 1	**Use of medical devices not to compromise health and safety** The manufacturer should undertake an analysis of the foreseeable risks that could occur from using the device and compare these with consideration of the benefits that would be provided for the patient or user of the medical device. These analyses must be documented and must recognise that a patient or user's safety is paramount.	✓	✓	✓	PAS 54115 IEC 62281 TGA guidance "Active medical devices" IEC 60601 series IEC 62366 CEN/TS 17633 E-Cigarettes, Vapes, and other Electronic Nicotine Delivery Systems US FDA
☐	EP 2	**Design and construction of medical devices to conform with safety principles** The manufacturer must identify hazards and associated risks arising from the use of the device, eliminate or reduce these risks as far as possible by design or other means, and inform the users of residual risks that may arise. A risk management report, which lists all identified hazards associated with the manufacture, distribution and use of the therapeutic vaping device is the normal way to document this process. A comprehensive hazard and risk analysis should be conducted for the device, considering both its use and foreseeable misuse, or incorrect use. This risk analysis should include the accessories used with the device as intended by the manufacturer. The report should include a final analysis of any remaining residual risks and their potential impact on device performance, health and safety. The whole product lifecycle should be considered (from design, verification, manufacturing, supply, to end user).	✓	✓	✓	PAS 54115 IEC 62281 TGA guidance "Active medical devices" IEC 60601 series IEC 62366 IEC 62304 CEN/TS 17633 GB 41700 UL 8139 IEC 62133-2 EN ISO 8317 E-Cigarettes, Vapes, and other Electronic Nicotine Delivery Systems US FDA

Cross here when you have evidence for this EP (☒)	EP No	EP Description	ISO 14971	ISO 20072	CEN/TS 17287	Other relevant standards and guidance documents
☐	EP 3	**Medical devices to be suitable for intended purpose** The therapeutic vaping device must perform in the way intended by the manufacturer and be designed, produced and packaged accordingly. The intended purpose and use of the device should be substantiated thoroughly using evidence such as pre-clinical testing, clinical evidence, usability studies, verification and validation evidence (including protocols, testing, analysis and reports).	✓	✓	✓	PAS 54115 IEC 62281 TGA guidance "Active medical devices" IEC 60601 series IEC 62366 ISO 14155 CEN/TS 17633 TGA Clinical Evidence Guidelines E-Cigarettes, Vapes, and other Electronic Nicotine Delivery Systems US FDA
☐	EP 4	**Long-term safety** The therapeutic vaping device must be designed and produced in a way that ensures that the device operates safely and reliably within the lifetime specified by the manufacturer. Compliance can be demonstrated by using appropriate evidence such as material and functional durability testing and long-term material stability testing.	✓	✓	✓	PAS 54115 IEC 62281 TGA guidance "Active medical devices" IEC 60601 series IEC 62366 E-Cigarettes, Vapes, and other Electronic Nicotine Delivery Systems US FDA

Cross here when you have evidence for this EP (☒)	EP No	EP Description	ISO 14971	ISO 20072	CEN/TS 17287	Other relevant standards and guidance documents
☐	EP 5	**Medical devices not to be adversely affected by transport or storage** The manufacturer must hold evidence to demonstrate the therapeutic vaping device is safe and performs as intended when used in foreseeable transport and storage scenarios. Typically, compliance is demonstrated through accelerated and real time studies that have been conducted to establish the shelf-life and transport stability of the therapeutic vaping device. Studies, testing or analysis should use comparable conditions to Australian climate zones or be modelled on them.	✓			ASTM F1980 ASTM F1886 ISTA 2A testing ASTM D5276 & D4169 UN 38.3, IEC 62133-2, IEC 62281
☐	EP 6	**Benefits of medical devices to outweigh any undesirable effects** The manufacturer must undertake a well-reasoned risk analysis supported by clinical investigations to provide an assessment of the benefit-risk profile for the therapeutic vaping device when it is used for its intended purpose. A safety profile can be established via clinical investigations, literature reviews and clinical experience (from post-market data, adverse event data).	✓			ISO 14155 TGA Clinical Evidence Guidelines
☐	EP 7	**Chemical, physical and biological properties** Compliance can be demonstrated through appropriate risk analysis and product testing for biocompatibility, leachable compounds, chemical compatibility with substances administered via the device.	✓	✓	✓	ISO 10993 series E-Cigarettes, Vapes, and other Electronic Nicotine Delivery Systems US FDA (not covering 7.2 and 7.7)
☐	EP 8	**Minimisation of risk of infection and contamination** Compliance can be demonstrated through appropriate process control measures and risk mitigation throughout the manufacture, storage and use of the device to ensure that risks of infection and contamination have been mitigated.	✓	✓	✓	ISO/DIS 23417 (as guidance)

Cross here when you have evidence for this EP (☒)	EP No	EP Description	ISO 14971	ISO 20072	CEN/TS 17287	Other relevant standards and guidance documents
☐	EP 9	**Construction and environmental properties** Compliance can be demonstrated through verifying the safety of the device when used in combination with its accessories, or components. Generally, usability studies and appropriate bench testing are used to demonstrate compliance.	✓	✓	✓	ISO 10993 series TGA guidance "Active medical devices" IEC 62366 UL 8139 UN 38.3, IEC 62133-2, IEC 62281, UL 1642 E-Cigarettes, Vapes, and other Electronic Nicotine Delivery Systems US FDA
☐	EP 12	**Medical devices connected to or equipped with an energy source** Compliance can be demonstrated through evidence of electrical system and battery safety. This should include electromagnetic compatibility and user safety through the product life cycle. If the device contains firmware, you should consider risks related to software, and the programmed or programmable elements of the device. Evidence of compliance in this case must demonstrate the safety, performance, reliability, accuracy, precision, useability, security and repeatability of the software or programmed or programmable subsystems of the device.	✓	✓	✓	TGA guidance "Active medical devices" IEC 60601 series IEC 62304 IEC 62366 AS/NZS 3112 UL 8139 IEC 62281 UL 2054 E-Cigarettes, Vapes, and other Electronic Nicotine Delivery Systems US FDA Consumer Goods (Products Containing Button/Coin Batteries) Safety Standard 2020

Cross here when you have evidence for this EP (☒)	EP No	EP Description	ISO 14971	ISO 20072	CEN/TS 17287	Other relevant standards and guidance documents
☐	EP 13	I**nformation to be provided with medical devices** Compliance can be demonstrated through showing that the Instructions for use, labelling and packaging are consistent with requirements for medical devices.	✓	✓	✓	ISO 15223-1 TGA guidance "Active medical devices" IEC 60601 series PAS 54115 GB 41700 ISO 28219 Consumer Goods (Products Containing Button/Coin Batteries) Safety Standard 2020
☐	EP 13B	**Software—version numbers and build numbers** Ensure that the current software version number and build number (where applicable) accessible and identifiable to users.	✓		✓	IEC/TR 80002-1 ISO 15223-1 TGA guidance "Active medical devices" IEC 62304 E-Cigarettes, Vapes, and other Electronic Nicotine Delivery Systems US FDA
☐	EP 14	**Clinical evidence** A detailed clinical performance report is required. See CER guidance. www.tga.gov.au/resources/resource/guidance/clinical-evidence-guidelines	✓			ISO 14155 TGA Clinical Evidence Guidelines

Glossary and further information on the standards:

The standards are considered the generally acknowledged state-of-the-art.

If you claim full compliance to a standard, you are claiming compliance with all the applicable clauses in the latest published version of that standard.

ISO 14971 - Medical devices Application of risk management to medical devices

This document specifies terminology, principles, and a process for risk management of medical devices, including software as a medical device. The process described in this document helps manufacturers of medical devices to identify the hazards associated with the medical device, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls.

ISO 20072 - Aerosol drug delivery device design verification - Requirements and test methods

ISO 20072 applies to the design, labelling, instructions for use and testing requirements for hand-held single- and multi-use aerosol drug delivery devices intended to deliver a metered or pre-metered aerosolized medication to or by means of the human respiratory tract (including nasal, oral, tracheal, bronchial, and alveolar sites). This International Standard applies to both refillable and disposable devices intended for personal use.

CEN/TS 17287 - Requirements and test methods for electronic cigarette devices

This standard specifies the minimum safety and technical requirements for electronic cigarette devices, e-liquid containers, and associated accessories when operated and maintained in the manner prescribed by the manufacturer.

PAS 54115 - Vaping products, including electronic cigarettes, e-liquids, e-shisha and directly-related products. Manufacture, importation, testing and labelling. Guide

This standard gives guidance for the manufacture, importation, labelling, marketing, and sale of vaping products including electronic cigarettes, e-shisha, do-it-yourself e-liquid mixing kits, and directly related products.

IEC 62281 Safety of primary and secondary lithium cells and batteries during transport

IEC 62281 specifies test methods and requirements for primary and secondary (rechargeable) lithium cells and batteries to ensure their safety during transport other than for recycling or disposal.

TGA guidance on active medical devices, Introduction and overview of requirements

TGA guidance on active medical devices provides guidelines on the requirements that specifically apply to active medical devices including requirements around electromedical safety standards, electrical safety and requirements for programmed and programmable medical devices.

IEC 60601 series

The IEC 60601 is a series of technical standards designed to ensure the safety and effectiveness of medical electrical equipment. You could use this standard as a guide to verify the electrical systems within the therapeutic vaping device to reduce risks to users such as electric shocks or burns.

IEC 62366 Medical devices Part 1: Application of usability engineering to medical devices

The is a process-based standard that specifies usability requirements for the development of medical devices.

CEN/TS 17633 General principles and requirements for testing of quality and nicotine levels of electronic cigarette liquids

This document can be used as guidance to verify vaping device long term performance and to ensure the device performs within set specifications. The standard provides guidance on analytical test methods to quantify the nicotine, propylene glycol and glycerol content in e-liquids by gas chromatography.

IEC 62304 Medical device software life cycle processes

IEC 62304 defines the life cycle requirements for software in a medical device and provides processes, activities, and tasks to ensure safety and performance of associated devices.

GB 41700 Mandatory National Standards for Electronic Cigarettes

The standard specifies the terms and definitions, requirements for design and raw materials, technical requirements, test methods, labelling and product instructions concerning electronic cigarettes.

UL 8139 Standard for Electrical Systems of Electronic Cigarettes and Vaping Devices

You could use this standard to help you assess if the electrical elements used in therapeutic vaping devices are safe for use. The standard specifies testing requirements for evaluation of the safety of the electrical, heating, battery and charging systems.

EN ISO 8317 Child-resistant packaging requirements and testing procedures for re-closable packages

This standard specifies performance requirements and test methods for re-closable packages designated as resistant to opening by children.

ISO 14155 Clinical investigation of medical devices for human subjects - Good clinical practice

This standard addresses good clinical practice for the design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the clinical performance or effectiveness and safety of medical devices.

TGA Clinical Evidence Guidelines

TGA Clinical evidence guidelines can provide guidance to manufacturers of therapeutic vaping devices and e-liquids on how to generate and evaluate clinical data to support the efficacy and safety of their products. The guidelines specify the type of evidence required, and help sponsors understand their regulatory obligations in relation to holding that evidence.

ASTM F1980 - Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices

You could use this standard as a guide to the development of evidence to show that the specified storage and distribution conditions of a vape does not affect safety or performance and to ensure the provision of specified storage and distribution conditions on the label and in the user instructions.

This standard provides guidance to verify time-related aspects of potential packaging integrity loss.

ISTA 2A - ISTA Series – International Safe Transit Association test procedures

This standard covers simulation testing of individual packaged products for shipment. Test procedure ISTA 2A is a partial simulation test for individual packaged therapeutic vaping devices which can be used to evaluate the performance of a packaged-product and compare relative performance of package and product design alternatives.

ASTM D5276 - Standard Test Method for Drop Test of Loaded Containers by Free Fall

This standard is intended for use in evaluating the ability of a container to withstand the sudden shock resulting from a free fall drop impact, or to evaluate the ability of a container and its inner packing to protect its contents during the sudden shock resulting from a free fall drop impact.

ASTM D4169 - Standard Practice for Performance Testing of Shipping Containers and Systems

This standard provides a guide for the evaluation of shipping units in accordance with a uniform system, using established test methods at levels representative of those occurring in actual distribution.

IEC 62133-2 - Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

This standard specifies requirements and tests for the safe operation of portable sealed secondary lithium cells and batteries containing non-acid electrolyte, under intended use and reasonably foreseeable misuse.

IEC 62281 - Safety of primary and secondary lithium cells and batteries during transport

The standard specifies test methods and requirements for primary and secondary (rechargeable) lithium cells and batteries to ensure their safety during transport other than for recycling or disposal.

UN 38.3 – Transportation testing for Lithium metal and lithium-ion batteries

This standard details environmental, mechanical, and electrical requirements for all lithium cells and batteries. This standard can be useful to demonstrate battery stability and stability of the device function is not affected after transportation.

ISO 10993 series - Biological evaluation of medical devices
ISO 10993 standards cover the general principles governing the biological evaluation of medical devices. These standards can be used to demonstrate the materials used in the device and its component are biocompatible and remain stable during storage and use of the devices and do not cause adverse reaction or irritation to the user.

E-Cigarettes, Vapes, and other Electronic Nicotine Delivery Systems (ENDS) | FDA
This US FDA guidance may not fully address EPs 7.2 and 7.7.
This guidance is intended to assist persons submitting premarket tobacco product applications for electronic nicotine delivery systems to the US FDA.

ISO/DIS 23417 - General specifications and validation methods for non-sterile medical device packages in good distribution practice principles This standard can be used as guidance to ensure the packaging and distribution of vapes does not affect the safety and performance of the vaping device.
The standard specifies the test methods of the validation and the performance of the distribution packaging for medical devices that do not need sterilization. This document is intended to facilitate harmonized regulatory requirements for transport packaging of medical devices in good distribution practice principles.

ISO 15223-1 - Symbols to be used with information to be supplied by the manufacturer
This document specifies symbols used to express information supplied for a medical device.

ISO 28219 – Packaging - Labelling and direct product marking with linear bar code and two-dimensional symbols
Standard covers both labels and direct marking of items.
This standard defines minimum requirements for labelling requirements to enable identifying of items and provides guidelines for item marking with machine-readable symbols, covers both labels and direct marking of items, includes testing procedures for label adhesive characteristics and mark durability and provides guidance for the formatting on the label of data presented in linear bar code, two-dimensional symbol or human-readable form.

Consumer Goods (Products Containing Button/Coin Batteries) Safety Standard 2020
This mandatory standard defines the safety requirements for all consumer goods containing button or coin batteries supplied in Australia, including storage containers and organisers.

IEC/TR 80002-1 - Medical Devices Software Package
This standard specifies the process of identifying, controlling, and monitoring risk and hazards associated with medical device software.

Version history

Version	Description of change	Author/s	Effective date
V1.0	Original publication	Therapeutic Goods Administration	March 2024